REMARKS

An Office Action was mailed in the above-captioned application on March 21, 2007. As of the Office Action, claims 67-94 were pending. Claims 67-73, 76, 80 and 82-94 were withdrawn from consideration. Claims 74, 75, 77-79 and 81 were rejected. This Request for Reconsideration document is submitted in response to said Office Action. Claims 74, 76, and 79 have been amended, Claim 75 has been cancelled, and new claims 95 and 96 have been added.

The Rejection under 35 U.S.C. § 102(b)

The Examiner has rejected Claims 74, 75, 77-79 and 81 under 35 U.S.C. 102(b) as being anticipated by Peltz, et al., *J. Immunol.* 141:1891-96 (1988). The Court of Appeals for the Federal Circuit has stated that anticipation requires the presence in a single prior art reference of each and every element of the claimed invention. *Lindemann Maschinenfabrik GMBH v. American Hoist & Derrick Co.*, 730 F.2d 1452, 1458 (Fed. Cir. 1984); *Alco Standard Corp. v. Tennessee Valley Auth.*, 1 U.S.P.Q.2d 1337, 1341 (Fed. Cir. 1986). "There must be no difference between the claimed invention and the reference disclosure, as viewed by a person of ordinary skill in the field of the invention." *Scripps Clinic v. Genentech Inc.*, 18 U.S.P.Q.2d 1001, 1010 (Fed. Cir. 1991) (citations omitted).

The rejection states that Applicant's arguments regarding the carbohydrate fusion component were unpersuasive to overcome the rejection.

Solely in the interest of expediting prosecution, Claim 74 has been amended to recite an isolated polypeptide having fusion component selected from the group consisting of an immunoglobulin, human serum albumin (HSA), Fc receptor, complement receptor, cytokine receptor, dextran and polyethylene glycol, and wherein the polypeptide is characterized in that;

(i) the Fc binding component retains biological activity and

(ii) the polypeptide has greater serum half life compared to the Fc binding component alone..

Amended claim 74 includes the features of claim 75, although "carbohydrate" has been omitted from the list of fusion components. In view of this amendment, claim 75 has been

cancelled. Support for this amendment can be found in original claim 75, and in the specification at page 15, line 31, to page 16, line 2 and page 16, lines 6-18.

New claims 95 and 96 have been added. Support for claim 95 can be found in original claim 75, and support for claim 96 can be found at page 17, lines 1 to 2. Since claims 95 and 96 depend from claim 74, and claim 74 is novel over Peltz, et al., it is submitted that claims 95 and 96 are also novel.

Reconsideration is respectfully requested.

The Rejection under 35 U.S.C. § 103(a)

The Examiner has rejected Claims 75 and 79 under 35 U.S.C. § 103(a) as being unpatentable over Peltz, et al., in view of Yeh, et al., *Proc. Natl. Acad. Sci. USA* 89:1904-1908 (1992). The Examiner bears the burden of establishing a prima facie case of obviousness (Section 103). In determining obviousness, one must focus on Applicant's invention as a whole. *Symbol Technologies Inc. v. Opticon Inc.*, 19 U.S.P.Q.2d 1241, 1246 (Fed. Cir. 1991).

Specifically, the rejection states that Peltz, et al., teach a polypeptide comprising an extracellular region of a native FcγRII receptor, but does not teach HSA. The rejection also states that Yeh, et al., teaches that due to certain characteristics of HSA, the "fusion of bioactive peptides to HSA is a plausible approach toward the design and recovery of secreted therapeutic HSA derivatives". The rejection further asserts that it would have been obvious to "combine the teachings of Peltz, et al., and Yeh, et al., to arrive at the fusion of soluble FcγRII linked to HSA as taught by Yeh, et al. with a reasonable expectation of success.

Applicant respectfully traverses this rejection. Claim 75 has been cancelled, however the limitations of Claim 75 have been introduced into claim 74, and Claim 79 has been amended to depend from Claim 74. Claim 74 further requires that the Fc binding component retains biological activity and the polypeptide has greater serum half life compared to the Fc binding component alone.

Despite the above-mentioned statement by Yeh, et al., and the rejection's conclusion that there would be a reasonable expectation of success in the combination of Peltz, et al., and Yeh, et al., and even assuming for the sake of argument that there is high skill in the art in the recombinant DNA technology of *making* a fusion protein (emphasis added), Applicant submits that it was actually *unpredictable* at the time of the invention, as to whether the claimed

polypeptide could be successfully produced such that the FcγRII component *retained biological activity*, an the polypeptide showed a *greater serum half life* compared to the FcγRII component alone. As previously submitted, it was *not* possible to predict these characteristics of the claimed polypeptide, which are now recited in amended claim 74, until the present inventors carried out the experimentation described at Example 6. Briefly, Yeh, et al., exemplifies the expression of a *single* fusion protein comprising a soluble CD4 receptor polypeptide fused to HSA. The extracellular region of FcγRII is dissimilar to the CD4 receptor investigated by Yeh, et al. The lack of similarity in the extracellular regions FcγRII and the CD4 receptor weighs against a reasonable expectation of success. With the possible exception of proteins closely related to CD4, the person skilled in the art would not have held any "reasonable expectation of success" in applying the teachings of Yeh, et al., in the fusing an FcγRII component (e.g. the soluble extracellular region of FcγRII) to HSA, or any other "fusion component", while maintaining the biological activity of that FcγRII component.

Further, the knowledge gained from the experimentation described in Example 6, and, particularly, the realization that a large fusion component such as HSA does not destroy the biological activity of the FcγRII component, subsequently led the inventors to investigate the expression of an FcγRII component with another fusion component, namely the bacterial maltose binding protein (43 kD) (see Example 12 , particularly, page 61, lines 15-22). This fusion protein, denoted C2MBPrsFcR, also proved to be successful inasmuch as the FcγRII component retained the ability to bind to immune complexes (i.e., *retained biological activity*). Taken together, these results allowed the present inventors to predict that an FcγRII component could be successfully expressed as a fusion protein comprising other fusion components such as immunoglobulin, polyethylene glycol and complement receptors, etc. (see the further discussion of other suitable fusion components at, for example, page 52, lines 7-37), which would be characterized in that the FcγRII component retained biological activity and the polypeptide showed a greater serum half life compared to the FcγRII component alone.

Given that the combined teachings of Peltz, et al., and Yeh, et al., provide no reasonable expectation of success in the provision of the fusion of soluble FcγRII linked to HSA, Applicant respectfully submits that the combination of Peltz, et al., and Yeh, et al., cannot render obvious amended claims 74 or 79. Reconsideration is respectfully requested.

Closing Remarks

Applicant believes that the pending claims are in condition for allowance. If it would be helpful to obtain favorable consideration of this case, the Examiner is encouraged to call and discuss this case with the undersigned.

This constitutes a request for any needed extension of time and an authorization to charge all fees therefore to deposit account No. 19-1970, if not otherwise specifically requested. The undersigned hereby authorizes the charge of any fees created by the filing of this document or any deficiency of fees submitted herewith to be charged to deposit account No. 19-1970.

Respectfully submitted,

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